

**DYNAMIC DEVICE THERAPY CONTROL FOR TREATING POST
MYOCARDIAL INFARCTION PATIENTS**

Cross-Reference to Related Applications

5 This application is related to co-pending, commonly assigned, U.S. Patent
Application No. 09/962,852, "EVOKED RESPONSE SENSING FOR ISCHEMIA
DETECTION," filed on September 25, 2001, U.S. Patent Application Serial No.
10/038,936, "METHOD AND APPARATUS FOR MEASURING LEFT
VENTRICULAR PRESSURE," filed on January 4, 2002, U.S. Patent Application
10 Serial No. 10/005,184, "METHOD AND APPARATUS FOR MINIMIZING POST-
INFARCT VENTRICULAR REMODELING," filed on December 5, 2001, U.S. Patent
Application Serial No. 10/314,910, "METHOD AND APPARATUS FOR
OPTIMIZING VENTRICULAR SYNCHRONY DURING DDD
RESYNCHRONIZATION THERAPY USING ADJUSTABLE ATRIO-
15 VENTRICULAR DELAYS," filed on December 9, 2002, U.S. Patent Application
Serial No. 10/314,899, "METHOD AND APPARATUS FOR OPTIMIZING STROKE
VOLUME DURING DDD RESYNCHRONIZATION THERAPY USING
ADJUSTABLE ATRIO-VENTRICULAR DELAYS," filed on December 9, 2002, and
U.S. Patent Application Serial No. 10/703,175 "A DUAL-USE SENSOR FOR RATE
20 RESPONSIVE PACING AND HEART SOUND MONITORING," filed on November
6, 2003, which are hereby incorporated by reference in their entirety.

Field of the Invention

25 This document generally relates to cardiac rhythm management systems and
particularly, but not by way of limitation, to such systems providing for cardiac pacing
after myocardial infraction.

Background

30 The heart is the center of a person's circulatory system. It includes an electro-
mechanical system performing two major pumping functions. The heart includes four

(LVEDP). One effect is the progressive change of the LV shape and size, a processes referred to as remodeling. Remodeling is initiated in response to a redistribution of cardiac stress and strain caused by the impairment of contractile function in the infarcted area as well as in nearby and/or interspersed viable myocardial tissue with lessened contractility due to the infarct. The remodeling starts with expansion of the infarcted area and progresses to a chronic, global expansion in the size and change in the shape of the entire LV. Although the process is initiated by the compensatory mechanism that increases cardiac output, the remodeling ultimately leads to further deterioration and dysfunction of the myocardium. Consequently, post MI patients experience impaired hemodynamic performance and have a significantly increased risk of developing heart failure.

For these and other reasons, there is a need to control post MI remodeling and improve hemodynamic performance.

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Summary

A cardiac rhythm management system includes an implantable device executing a dynamic pacing algorithm after a myocardial infarction (MI) event. The dynamic pacing algorithm provides for improved hemodynamic performance when a person's metabolic need is high and post MI remodeling control when the person's metabolic need is low.

In one embodiment, an implantable medical device includes a sensing circuit, a pacing circuit, an activity sensor, and a pacing controller. The sensing circuit senses at least one electrogram. The pacing circuit delivers pacing pulses. The activity sensor senses an activity level. The pacing controller includes a dynamic pacing parameter controller, an MI detector, and a pacing algorithm selector. The dynamic pacing parameter controller receives an activation signal and, after the activation signal is received, controls one or more pacing parameters based on at least the activity level. The MI detector detects a signal indicative of an MI event. The pacing algorithm selector generates the activation signal after the signal indicative of the MI event is detected. In a further embodiment, a cardiac rhythm management system includes the

FIG. 1 is a flow chart illustrating an embodiment of a method for post MI cardiac pacing.

FIG. 2 is an illustration of an embodiment of a cardiac rhythm management (CRM) system and portions of an environment in which it is used.

5 FIG. 3 is a block diagram showing one embodiment of portions of the circuit of an implantable device of the CRM system.

FIG. 4 is a block diagram showing one embodiment of portions of the circuit of the implantable device and portions of the circuit of an external system of the CRM system.

10 FIG. 5 is a block diagram showing one further embodiment of portions of the circuit of the implantable device and portions of the circuit of the external system of the CRM system.

FIG. 6 is a flow chart illustrating an embodiment of a method for operating an implantable medical device to deliver post MI cardiac pacing.

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Detailed Description

In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that the embodiments may be combined, or that other embodiments may be utilized and that structural, logical and electrical changes may be made without departing from the spirit and scope of the present invention. The following detailed description provides examples, and the scope of the present invention is defined by the appended claims and their equivalents.

20 It should be noted that references to “an”, “one”, or “various” embodiments in this disclosure are not necessarily to the same embodiment, and such references contemplate more than one embodiment.

This document discusses, among other things, a method and system for delivering cardiac pacing therapy to post MI patients. Many post MI patients need both

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maximize hemodynamic performance. One therapy for treating post MI patients is to control the progress of post MI remodeling by reducing the preload in the infract region. Pacing pulses are delivered with a short atrioventricular (AV) delay to reduce the stress to this region prior to contraction. However, pacing with the short AV delay may result in reduced hemodynamic performance. For example, if the heart being paced with the short AV delay has a normal ventricular conduction (Purkinje) system, the pacing lowers measures of hemodynamic performance such as the degree of ventricular synchrony and the cardiac output. One consequent problem is that when a post MI patient becomes active, the pacing with the short AV delay may limit the cardiac output and hence, prevent the heart from pumping sufficient blood to meet the patient's metabolic need. One solution is to deliver the CRT and RCT on an alternating basis, depending on the metabolic need of the post MI patient, such that the pacing provides for optimal hemodynamic performance when the metabolic need is high, and post MI remodeling control when the metabolic need is low. In other words, a comprehensive therapy is delivered by executing a dynamic pacing algorithm, and that includes executing at least two specific pacing algorithms, such as the CRT and RCT pacing algorithms, on an alternating basis.

As illustrated in FIG. 1, an activity level is sensed at 100. The activity level is a measure of the intensity of the patient's gross physical activity, which in turn indicates the patient's metabolic need for oxygenated blood. In one embodiment, an acceleration signal is sensed as the activity level, such as by using an accelerometer implanted in the patient. In another embodiment, the patient's minute ventilation is sensed as the activity level, such as by using an impedance sensor implanted in the patient. In another embodiment, the heart rate of the patient is sensed as the activity level from an electrocardiogram or electrogram. The heart rate is usable as an indication of the activity level when it is an intrinsic heart rate, such as when the patient receives VDD mode pacing.

The activity level is compared to a predetermined threshold at 110. The threshold corresponds to an activity level above which a need to improve or maintain hemodynamic performance is indicated. The threshold is determined based on the

It is to be understood that the CRT and RCT are used to illustrate the method by way of example, but not by way of limitation. The method discussed herein using the CRT and RCT as examples applies to a pacing therapy with two or more pacing algorithms dynamically selected and executed to serve a plurality of therapy objectives.

5 In general, the method discussed above, using the CRT, RCT, and activity level as examples, is generally applicable to a comprehensive treatment of a patient with any abnormal condition, where the comprehensive treatment includes a first therapy, a second therapy, and a signal or parameter indicating when the first therapy is to be delivered and when the second therapy is to be delivered.

10 FIG. 2 is a schematic/block diagram illustrating one embodiment of portions of a CRM system 200 and portions of the environment in which it is used. CRM system 200 includes a cardiac pacing system to perform the method discussed above with reference to FIG. 1. In one embodiment, CRM system 200 includes an implantable system 235, an external system 255, and a telemetry link 245 providing for bidirectional
15 communication between implantable system 235 and external system 255. Implantable system 235 includes an implantable device 240 and an implantable lead system 210. Implantable device 240 is implanted within a body 202 and electrically connected to a heart 201 via lead system 210. Implantable device 240 is an implantable pacemaker or any implantable medical device with a pacemaker circuit, such as a pacemaker-
20 defibrillator. In one embodiment, the implantable pacemaker provides for the CRT pacing and RCT pacing. In one embodiment, lead system 210 includes an atrial pacing lead having one or more electrodes placed in the right atrium, and one ventricular pacing lead having one or more electrodes placed in a ventricle. In another embodiment, multiple ventricular sites are paced, and lead system 210 includes multiple
25 ventricular pacing leads each having one or more electrodes to be placed in the LV and/or the RV.

In one embodiment, external system 255 is a patient management system including an external device 250 in proximity of implantable device 240, a remote device 270 in a relatively distant location, and a telecommunication network 260
30 linking external device 250 and remote device 270. The patient management system

least the ventricular site with a programmable AV delay. In one embodiment, sensing circuit 320 senses electrograms from an atrial region and a plurality of ventricular regions. Pacing circuit 322 delivers pacing pulses to one or more of the ventricular regions, with individually programmable AV delays. Each region corresponds to at least one electrode site. When pacing pulses are delivered to two or more ventricular regions, the timing of the delivery is controlled with either individually controlled AV delays or with one AV delay and one or more interventricular delays. For example, if pacing pulses are delivered to an RV site and an LV site, in one embodiment, RV pacing pulses are each delivered with an AV delay for RV, AVD_{RV} , and LV pacing pulses are each delivered with an AV delay for LV, AVD_{LV} . In an alternative embodiment, RV pacing pulses are each delivered with an AV delay for RV, AVD_{RV} , and LV pacing pulses are each delivered with an interventricular delay between RV and LV, IVD_{LV-RV} , where $IVD_{LV-RV} = AVD_{LV} - AVD_{RV}$.

Activity sensor 324 senses an activity level being a measure of the intensity of the patient's gross physical activities. In one embodiment, activity sensor 324 includes a heart rate monitor to detect a heart rate indicative of the activity level. In one specific embodiment, the heart rate monitor includes an event detector to detect ventricular contractions from a ventricular electrogram, measures the time interval between two consecutively detected ventricular contractions, and calculates the heart rate based on the time interval. In another specific embodiment, the heart rate monitor includes an event detector to detect atrial contractions from an atrial electrogram, measures the time interval between two consecutively detected atrial contractions, and calculates the heart rate based on the time interval. In one embodiment, activity sensor 324 includes an accelerometer to sense an acceleration signal indicative of the activity level. In one specific embodiment, the accelerometer is housed within the hermetically sealed can. In another specific embodiment, the accelerometer is incorporated into a lead of lead system 210, so as to be placed near or within the heart. In one embodiment, activity sensor 324 includes a respiratory sensor to sense a signal indicative of the patient's minute ventilation. In one specific embodiment, the respiratory sensor is an impedance sensor sensing thoracic impedance indicative of the pulmonary volume.

channels as they are programmed into implantable device 240. Dynamic pacing parameter controller 332 includes an activity level comparator to compare the sensed activity level to a threshold level indicative of a need for the pacing parameter adjustment. In one embodiment, the activity level comparator compares the sensed activity level to one or more predetermined activity level thresholds to produce two or more activity level ranges. Each activity level range corresponds to a predetermined set of one or more pacing parameter values. In one embodiment, such as in the example of the alternating execution of the CRT and RCT pacing algorithms, each predetermined set of one or more pacing parameter values corresponds to one of the pacing algorithms being part of a dynamic pacing algorithm. In this embodiment, dynamic pacing parameter controller 332 effectively switches pacing algorithms by adjusting pacing parameters. In one specific embodiment, dynamic pacing parameter controller 332 changes the pacing algorithm being executed from the CRT pacing algorithm to the RCT pacing algorithm by shortening one or more AV delays, adjusting one or more interventricular delays, and/or reselecting one or more pacing channels.

Pacing algorithm selector 334 selects one or more pacing algorithms to be executed by pacing controller 330 in response to an algorithm selection signal. When the algorithm selection signal calls for a dynamic pacing algorithm which requires dynamic pacing parameter adjustments during the execution, pacing algorithm selector 334 generates an activation signal to activate dynamic pacing parameter controller 332. In one embodiment, pacing algorithm selector 334 includes a timer to time a predetermined time period starting with the MI event and generates the activation signal after the predetermined period expires. Because post MI remodeling progresses in stages, a post MI RCT pacing is timed to start and/or be adjusted at appropriate times.

MI detector 336 detects a signal indicative of an MI event and produces the algorithm selection signal calling for the dynamic pacing algorithm in response to a detection. Thus, pacing algorithm selector 334 generates the activation signal to activate dynamic pacing parameter controller 332 after the signal indicative of the MI event is detected. In one embodiment, MI detector 336 includes a command receiver to receive an external activation command sent to implantable device 240 as the signal

FIG. 4 is a block diagram showing one embodiment of portions of the circuit of implantable device 240 and portions of the circuit of external system 255. Implantable device 240 communicates with external system 255 via telemetry link 245.

External system 255 includes a user input 456 to receive commands from the physician or other caregiver controlling operations of implantable device 240. User input 456 receives a user activation command and issues the external activation command, which is transmitted to implantable device 240 via telemetry 245. In one embodiment, user input 456 also receives values for the pacing parameters such as the preset AV delays, interventricular delays, and pacing channels. In one embodiment, user input 456 includes an on/off selector allowing an entry of the user activation command by an on-selection. In another embodiment, user input 456 includes toggle switch allowing an entry of the user activation command by switching to the on-position. In one embodiment, user input 456 includes numerical entry fields to receive values for the pacing parameters, such as the preset AV delay values, the preset interventricular delay values, and the preset pacing channels. The pacing parameter values are programmed into pacing controller 330 of implantable device 240 via telemetry.

In one embodiment, external system 255 includes a programmer with user input 456. In another embodiment, external system 255 is a patient management system including external device 250, network 260, and remote device 270. In one embodiment, external device 250 includes user input 456 to allow the physician or other caregiver to enter the external activate command and/or the preset pacing parameter values in the presence of the patient. In one embodiment, remote device 270 includes user input 456 to allow the physician or other caregiver to enter the external activate command and/or the preset pacing parameter values from a remote location, eliminating the need of directly seeing the patient before delivering a new therapy.

FIG. 5 is a block diagram showing one further embodiment of portions of the circuit of implantable device 240 and portions of the circuit of external system 255. In this embodiment, implantable device 240 further includes a hemodynamic performance sensor 526 to sense a signal indicative of hemodynamic performance. In one

pressure analyzer to calculate the maximum positive derivative of the LV pressure, denoted by the term "LV+dp/dt." LV+dp/dt is a measure of LV synchrony, also known LV contractility. The LV pressure is measured directly or indirectly by sensing another pressure having a known or predictable relationship with the LV pressure. Examples of pressures having known or predictable relationships with the LV pressure during all or a portion of the cardiac cycle include an LA pressure and a coronary vein pressure. One specific example of measuring the LV pressure using a coronary vein pressure sensor is discussed in U.S. Patent Application Serial No. 10/038,936, "METHOD AND APPARATUS FOR MEASURING LEFT VENTRICULAR PRESSURE," filed on January 4, 2002, assigned to Cardiac Pacemakers, Inc., which is hereby incorporated by reference in its entirety. In one embodiment, such as a CRT, one or more pacing parameters are optimized for a maximum LV+dp/dt.

In one embodiment, hemodynamic performance sensor 526 includes a stroke volume sensor to sense a signal indicative of a stroke volume. An example of stroke volume sensing is discussed in U.S. Patent No. 4,686,987, "BIOMEDICAL METHOD AND APPARATUS FOR CONTROLLING THE ADMINISTRATION OF THERAPY TO A PATIENT IN RESPONSE TO CHANGES IN PHYSIOLOGIC DEMAND," assigned to Cardiac Pacemakers, Inc., which is incorporated herein by reference in their entirety. In one embodiment, such as a CRT, one or more pacing parameters are optimized for a maximum stroke volume.

In the embodiment of FIG. 5, external system 255 further includes a signal receiver 558, a presentation device 557, and an external controller 559. Signal receiver 558 receives signals acquired by implantable device 240, including one or more electrograms, the activity level, and the signal indicative of hemodynamic performance. Presentation device 557 presents the received signals to the physician or other caregiver. In one embodiment, the physician or other caregiver responds by entering the user activation command and/or the pacing parameter values through user input 456. In one embodiment, external controller 559 analyzes the received signals and automatically issues the external activation command when deemed necessary.

pacing parameters are adjusted based on the outcome of the comparison. In one embodiment, the one or more pacing parameters to be dynamically adjusted include at least one AV delay. In another embodiment, the one or more pacing parameters to be dynamically adjusted include at least one AV delay and one interventricular delay. In one specific embodiment, the AV delay and/or interventricular delay are adjusted by selecting from a plurality of preset AV delay and/or interventricular delay values based on at least the activity level. In one embodiment, the one or more pacing parameters to be dynamically adjusted include pacing channels. One or more pacing channels are selected from a set of cardiac sites where pacing electrodes are placed.

10 In one embodiment, a signal indicative of the patient's hemodynamic performance is sensed. In one embodiment, the signal indicative of the patient's hemodynamic performance is used to determine the one or more pacing parameters such as the AV delay, interventricular delay, and pacing channels. In one embodiment, the signal indicative of the patient's hemodynamic performance is used to determine whether the dynamic pacing algorithm should be executed. In one further embodiment, the signal indicative of the patient's hemodynamic performance is used to determine whether the execution should be interrupted or stopped. Examples of the signal indicative of the hemodynamic performance include the patient's minute ventilation, S1 amplitude and duration, S3 amplitude, LV+dp/dt, and stroke volume.

20 It is to be understood that the above detailed description is intended to be illustrative, and not restrictive. For example, the method of automatically and selectively executing two or more therapy algorithms can be applied to treat non-cardiac conditions, and not necessarily by using an implantable device. Other embodiments, including any possible permutation of the system components discussed in this document, will be apparent to those of skill in the art upon reading and understanding the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

6. The implantable pacemaker of claim 1, wherein the dynamic pacing parameter controller comprises an atrioventricular (AV) delay adjuster adapted to dynamically adjusting at least one AV delay based on at least the activity level.
- 5 7. The implantable pacemaker of claim 6, wherein the AV delay adjuster comprises an AV delay selector to dynamically select a value for the at least one AV delay from a plurality of predetermined AV delay values based on at least the activity level.
- 10 8. The implantable pacemaker of claim 6, wherein the dynamic pacing parameter controller further comprises an interventricular delay adjuster adapted to dynamically adjusting at least one interventricular delay based on at least the activity level.
- 15 9. The implantable pacemaker of claim 8, wherein the interventricular delay adjuster comprises an interventricular delay selector to dynamically select a value for the at least one interventricular delay from a plurality of predetermined interventricular delay values based on at least the activity level.
- 20 10. The implantable pacemaker of claim 6, wherein the pacing circuit comprises a plurality of pacing channels to deliver the pacing pulses to a plurality of cardiac sites, and the dynamic pacing parameter controller comprises a pacing channel selector adapted to dynamically select a predetermined set of one or more pacing channels from the plurality of pacing channels based on at least the activity level.
- 25 11. The implantable pacemaker of claim 10, further comprising an activity level comparator to compare the activity level to one or more predetermined activity level thresholds, wherein the dynamic pacing parameter controller is adapted to control one or more pacing parameters based on at least the result of the comparison.

20. The implantable pacemaker of claim 19, wherein the pacing controller comprises a signal analyzer to receive the signal indicative of hemodynamic performance, and the pacing algorithm selector determines whether to activate or deactivate the dynamic pacing parameter controller based on the signal indicative of hemodynamic performance.
21. The implantable pacemaker of claim 20, wherein the hemodynamic performance sensor comprises an impedance sensor sensing a signal indicative of minute ventilation.
22. The implantable pacemaker of claim 20, wherein the hemodynamic performance sensor comprises an acoustic sensor to sense heart sounds and a heart sound analyzer to detect first heart sounds (S1) and measure an S1 duration.
23. The implantable pacemaker of claim 20, wherein the hemodynamic performance sensor comprises a pressure sensor to sense a signal indicative of a left ventricular pressure and a pressure analyzer to calculate an maximum positive derivative of the left ventricular pressure, $LV+dp/dt$.
24. The implantable pacemaker of claim 20, wherein the hemodynamic performance sensor comprises a stroke volume sensor to sense a signal indicative of stroke volume.
25. A cardiac rhythm management system, comprising:
an implantable medical device including:
a sensing circuit to sense at least one electrogram;
a pacing circuit to deliver pacing pulses;
an activity sensor to sense an activity level; and
a pacing controller coupled to the sensing circuit, the pacing circuit, and the activity sensor, the pacing controller including:

30. The cardiac rhythm management system of claim 29, wherein the hemodynamic performance sensor comprises the activity sensor.
- 5 31. The cardiac rhythm management system of claim 29, wherein the external system comprises a signal receiver to receive one or more of the at least one electrogram, the activity level, and the signal indicative of hemodynamic performance.
- 10 32. The cardiac rhythm management system of claim 31, wherein the external system comprises a presentation device to present the received one or more of the at least one electrogram, the signal indicative of hemodynamic performance.
- 15 33. The cardiac rhythm management system of claim 31, wherein the external system comprises an external controller to issue the external activation command based on the received one or more of the at least one electrogram, the signal indicative of a measure of hemodynamic performance.
- 20 34. The cardiac rhythm management system of claim 31, wherein the external system comprises a programmer.
- 25 35. The cardiac rhythm management system of claim 31, wherein the external system comprises:
an external device coupled to the implantable medical device via telemetry;
a network coupled to the external device; and
a remote device coupled to the network.
36. The cardiac rhythm management system of claim 35, wherein the remote device comprises the presentation device and the user input.

44. The method of claim 43, wherein dynamically adjusting the at least one interventricular delay comprises dynamically selecting a value for the at least one interventricular delay from a plurality of predetermined interventricular delay values
5 based on at least the activity level.

45. The method of claim 41, wherein dynamically adjusting the one or more pacing parameters further comprises dynamically selecting one or more pacing channels from a plurality of predetermined pacing channels based on at least the activity level.
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46. The method of claim 37, wherein dynamically adjusting the one or more pacing parameters comprises comparing the activity level to one or more predetermined threshold levels and adjusting the one or more pacing parameters based on at least the result of the comparison.
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47. The method of claim 37, wherein executing the dynamic pacing algorithm comprises:
timing a predetermined time period starting when the signal indicative of the myocardial infarction event is detected; and
20 starting to execute the dynamic pacing algorithm upon an expiration of the predetermined time period.

48. The method of claim 37, wherein detecting the signal indicative of the myocardial infarction event comprises receiving an external activation command from
25 an external system communicating to the implantable pacemaker, the external activation command being the signal indicative of the myocardial infarction event.

49. The method of claim 48, further comprising receiving values for the one or more pacing parameters from the external system.

59. The method of claim 54, wherein sensing the signal indicative of hemodynamic performance comprises sensing a signal indicative of a left ventricular pressure and calculating an maximum positive derivative of the left ventricular pressure, $LV+dp/dt$.
- 5 60. The method of claim 54, wherein sensing the signal indicative of hemodynamic performance comprises sensing a signal indicative of stroke volume.
61. The method of claim 54, further comprising transmitting the at least one electrogram, the activity level, and the signal indicative of hemodynamic performance
10 to an external system communicating with the implantable pacemaker via telemetry.
62. A cardiac pacing method, comprising:
sensing an activity level;
comparing the activity level to a predetermined threshold;
15 executing a cardiac resynchronization therapy (CRT) pacing algorithm if the activity level exceeds the predetermined threshold; and
executing a remodeling control therapy (RCT) pacing algorithm if the activity level does not exceed the predetermined threshold.
- 20 63. The method of claim 62, wherein sensing the activity level comprises sensing an acceleration.
64. The method of claim 62, wherein sensing the activity level comprises sensing a minute ventilation.
25
65. The method of claim 62, wherein sensing the activity level comprises sensing a heart rate.

**DYNAMIC DEVICE THERAPY CONTROL FOR TREATING POST
MYOCARDIAL INFARCTION PATIENTS**

Abstract

5 A cardiac rhythm management system includes an implantable device executing
a dynamic pacing algorithm after an myocardial infarction (MI) event. The dynamic
pacing algorithm dynamically adjusts one or more pacing parameters based on a
person's gross physical activity level. Examples of the one or more pacing parameters
include atrioventricular pacing delays and pacing channels/sites. The dynamic pacing
10 algorithm provides for improved hemodynamic performance when a person's metabolic
need is high, and post MI remodeling control when the person's metabolic need is low.

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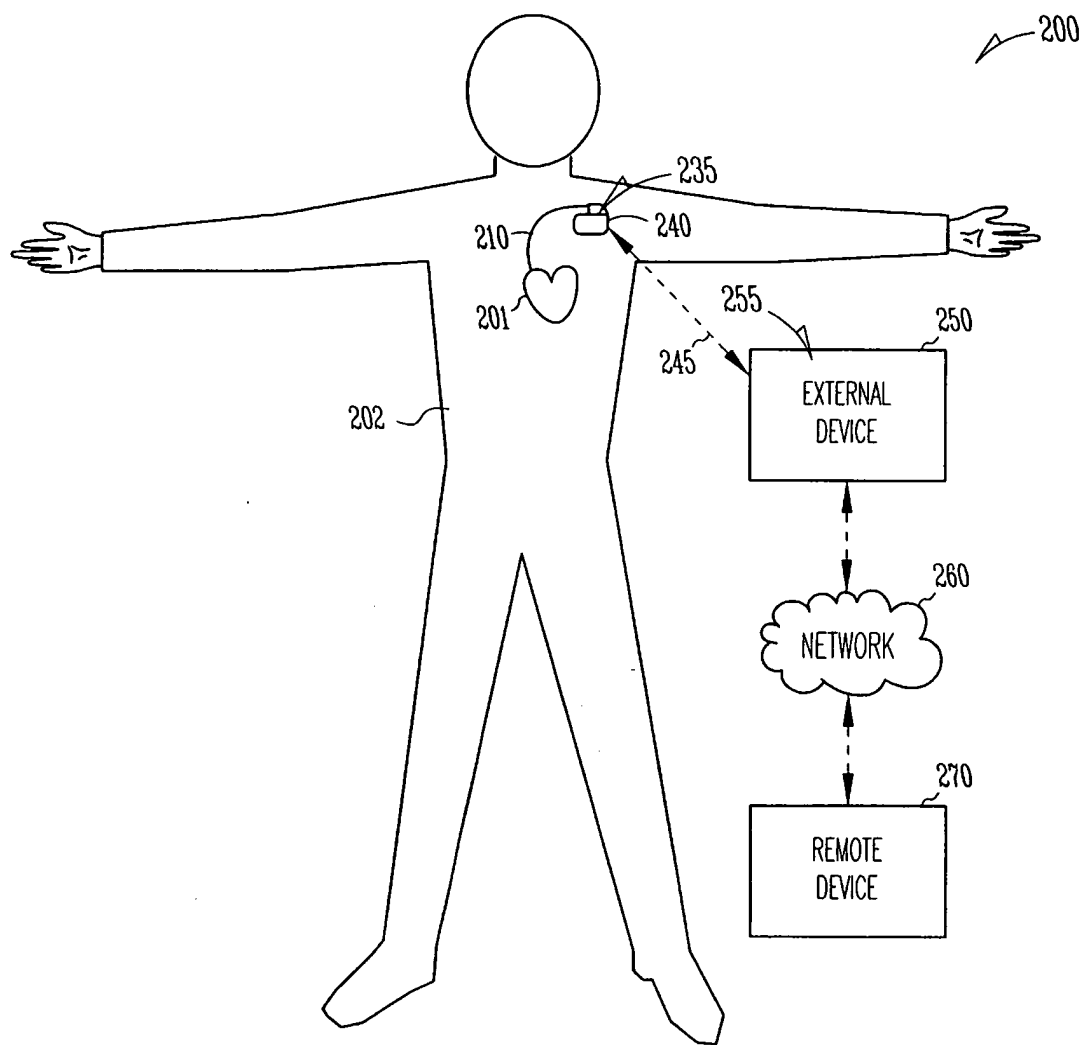


Fig. 2

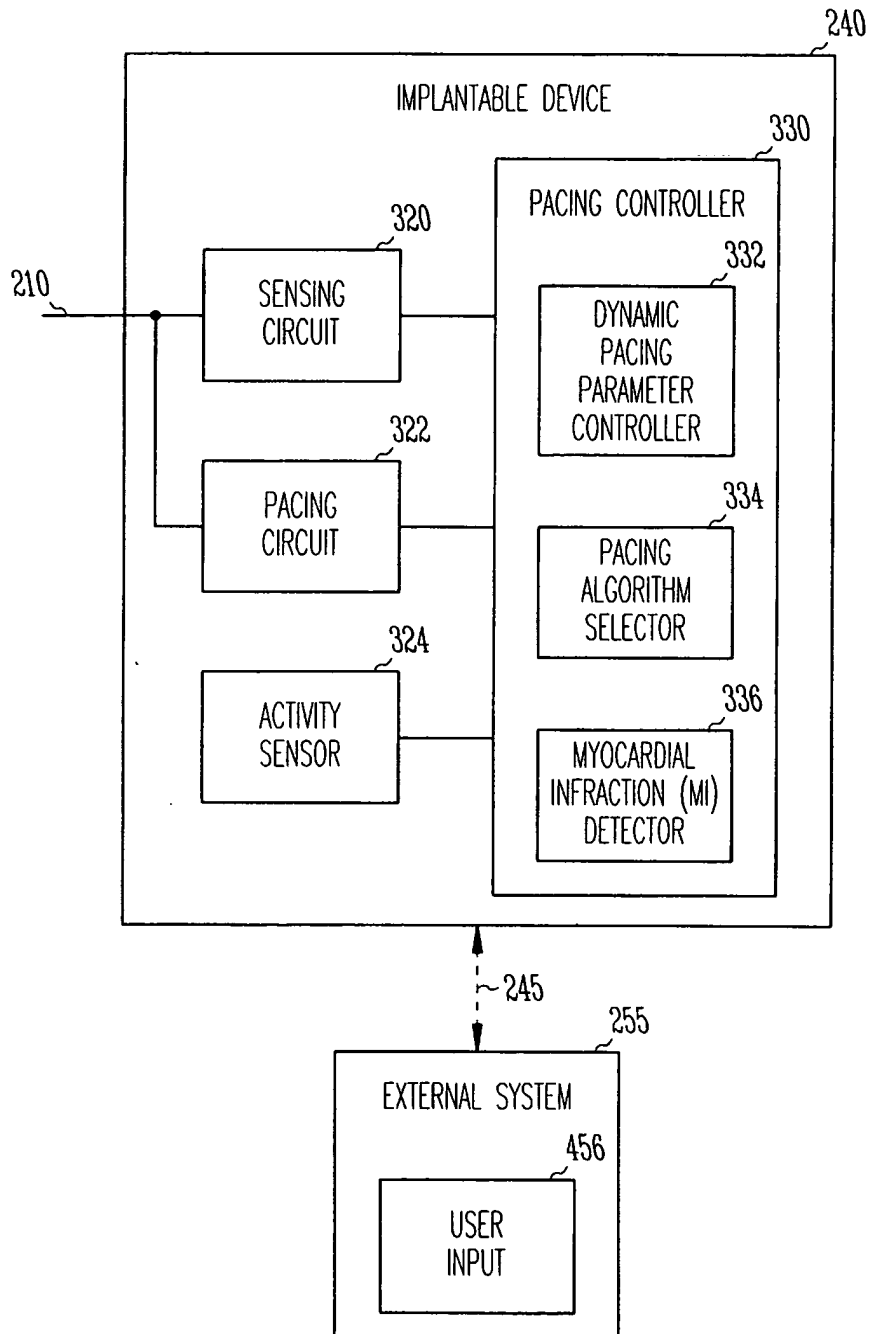


Fig. 4

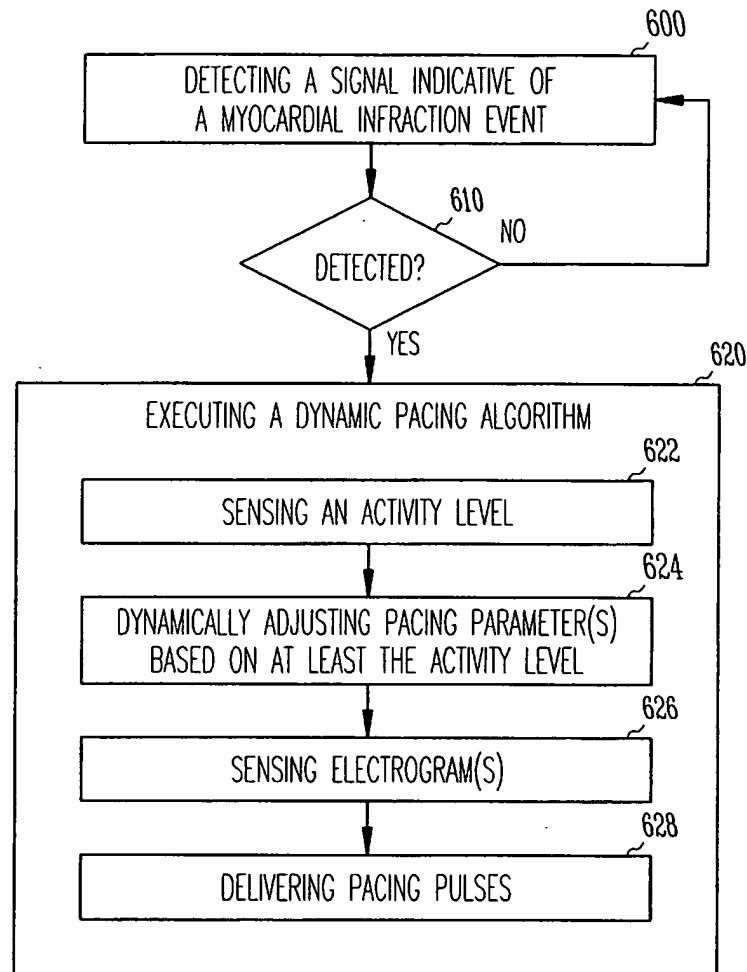


Fig. 6